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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/028,989	12/28/2001	Ronald J. Pettis	7767-177409	4392

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EXAMINER	
BOUCHELLE, LAURA A	

ART UNIT	PAPER NUMBER
3763	

MAIL DATE	DELIVERY MODE
08/19/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/028,989	PETTIS ET AL.	
	Examiner	Art Unit	
	LAURA A. BOUCHELLE	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 February 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *69-75,77-79,81-95 and 97-105* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *69-75,77-79,81-95 and 97-105* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/26/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 69-75, 77-79, 81-84, 88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gross (US 5848991) in view of Silverman et al (US 5478328) in further view of D'Antonio et al (US 60567116). Gross discloses a method of delivering drugs intradermally using a single needle with an outlet at a depth of 250 um - 2mm in a controlled manner based on needle diameter (Col. 4, lines 10-35). Gross discloses that the delivery can be infusion, pulsatile, or intermittent doses (Col. 4, 1ines 49-53) and that the dose rate can be varied as per the individual or drug type delivered needs (Co1. 4, lines 55-57; Col. 5, lines 26-30; Col. 8, lines 13-15). A pulsatile delivery will administer the drug over a short period of time, i.e. not more than 10 minutes. Upon delivering medication to the intradermal compartment, the physiology of this location causes the improved systemic absorption as compared to transdermal injections (Col. 3, lines 38-44). This limitation suggests that there is improved systemic absorption.

3. The drug may be a peptide, a hormone, or insulin (col.6, lines 56 – col. 7, line 20).

4. Claims 1, 88 differ from Gross in calling for the outlet to have an exposed height between 0 and 1 mm. Silverman teaches that the intradermal needle available from Beckton-Dickinson at the time of invention has a very slight bevel which assists the user in accessing only the intradermal space. Therefore, it would have been obvious to one of ordinary skill in

the art at the time of invention to modify the device of Gross to include a 0 to 1 mm bevel for an intradermal access needle because that is a known bevel length for an intradermal needle at the time of invention.

5. Gross does not expressly disclose that the intradermal delivery achieves improved bioavailability relative to the bioavailability upon injecting subcutaneously. D'Antonio (Col. 3, lines 27-28; Col. 29, lines 3-26) suggests that medication delivered intradermally results in improved bioavailability and therefore "greatly reduced volumes" of the injectant are necessary. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of D'Antonio in the method of Gross in order to achieve a therapeutic result using less drug. The cost savings and ability to effectively deliver scarce drugs to a larger number of people would motivate one of ordinary skill in the art to modify the method of Gross with the teachings of D'Antonio.

6. Regarding claims 69, 77, 78, D'Antonio fails to expressly disclose that the dosage is reduced by at least 10%, 20% or 30%. However, D'Antonio clearly states that delivery to the intradermal compartment "greatly" reduces the necessary volume of the injectant. Furthermore, the reduction of the dosage by 10% to achieve bioavailability is a direct result of delivering the drug through a needle as claimed. Therefore, by meeting the claimed limitation, the teachings of Gross in view of D'Antonio inherently provide the claimed reduction of dosage to achieve availability.

7. The teachings above fail to teach that the systemic bioavailability is measured by a determination of its AUC. This limitation is not interpreted to be a positive recitation of a method step. Determining AUC is a well known method of measuring systemic bioavailability.

Therefore, one of skill in the art at the time of invention would have known that the systemic bioavailability could be determined by measuring AUC or any other known method in the art.

8. Claims 85-87, 89, 93-95, 97-105 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gross (US 5848991) in view of D'Antonio et al (US 60567116). Regarding claim 85, 86, 89, 93-95, 97-105, see the discussion of Gross and D'Antonio above. Regarding claim 87, the needle has a diameter which corresponds to approximately a 33-34 gauge needle.

1. Claims 85, 90-92 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al (USPN 5,250,023) in view of D'Antonio.

Lee discloses an intradermal compartment drug delivery device that includes administering a substance through a small gauge hollow needle array of at least 6 needles (4 and 14). The length of the needle is between 0.3 to 2.0 mm. The substances for injection include a variety of substances that include peptides and proteins. As shown in figures 1-2, the needle is inserted perpendicularly into the skin.

9. Lee does not expressly disclose that the intradermal delivery achieves improved bioavailability relative to the bioavailability upon injecting subcutaneously. D'Antonio (Col. 3, lines 27-28; Col. 29, lines 3-26) suggests that medication delivered intradermally results in improved bioavailability and therefore "greatly reduced volumes" of the injectant are necessary. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of D'Antonio in the method of Lee in order to achieve a therapeutic result using less drug. The cost savings and ability to effectively deliver scarce drugs to a larger number of people would motivate one of ordinary skill in the art to modify the method of Gross with the teachings of D'Antonio.

10. Regarding claims 85 D'Antonio fails to expressly disclose that the dosage is reduced by at least 10%, 20% or 30%. However, D'Antonio clearly states that delivery to the intradermal compartment "greatly" reduces the necessary volume of the injectant. Furthermore, the reduction of the dosage by 10% to achieve bioavailability is a direct result of delivering the drug through a needle as claimed. Therefore, by meeting the claimed limitation, the teachings of Lee in view of D'Antonio inherently provide the claimed reduction of dosage to achieve availability.

11. The teachings above fail to teach that the systemic bioavailability is measured by a determination of its AUC. This limitation is not interpreted to be a positive recitation of a method step. Determining AUC is a well known method of measuring systemic bioavailability. Therefore, one of skill in the art at the time of invention would have known that the systemic bioavailability could be determined by measuring AUC or any other known method in the art.

Response to Arguments

2. Applicant's arguments, see arguments, filed 2/6/09, with respect to the rejection(s) of claim(s) under Gross in view of Srivatava have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Gross or Lee in view of D'Antonio.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA A. BOUCHELLE whose telephone number is (571)272-2125. The examiner can normally be reached on Monday-Friday 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763

Laura A Bouchelle
Examiner
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